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Attorney Docket No. 71745/55913

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Butt *et al.*

GROUP: 1636

U.S.S.N.: 09/856,336

EXAMINER: Sandals, W.

FILED: August 20, 2001

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FOR: NUCLEIC ACID ISOLATION

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CERTIFICATE OF MAILING

I hereby certify this correspondence and the documents referred to as attached herein are being deposited with the United States Postal Service as First Class Mail addressed to Assistant Commissioner for Patents, Washington, D.C. 20231 on March 14, 2003.

By: Nicole M. McKinnon
Nicole M. McKinnon

Sir:

TRANSMITTAL

Transmitted herewith for filing in the above-referenced patent application are the following documents:

- 1) Notice of Appeal (3 pages);
- 2) Petition and Fee for Extension of Time (2 pages);
- 3) Copy of Office Action mailed November 19, 2002 (7 pages);
- 4) Amendment (21 pages);
- 5) Check #710608 in the amount of \$430.00 representing the 1-month extension fee (\$110.00) and Notice of Appeal fee (\$320.00); and
- 6) Return Postcard

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,336	08/20/2001	Neil James Butt	7174555913	6843
7590	11/19/2002			
David G Conlin Dike Bronstein Roberts & Cushman Edwards & Angell PO Box 9169 Boston, MA 02109			EXAMINER [REDACTED]	SANDALS, WILLIAM O
			ART UNIT 1636	PAPER NUMBER 8
			DATE MAILED: 11/19/2002	

COPY

Please find below and/or attached an Office communication concerning this application or proceeding.

MAR 20 2003
U.S. PATENT & TRADEMARK OFFICE
JC425

for WT/ny

Office Action Summary

Application No.	Applicant(s)	
09/856,336	Butt et al.	
Examiner William Sandals	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Aug 26, 2002

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-38 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-12, 15-29, 32, 33, 36, and 38 is/are rejected.

7) Claim(s) 13, 14, 30, 31, 34, 35, and 37 is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

- 1. Certified copies of the priority documents have been received.
- 2. Certified copies of the priority documents have been received in Application No. _____.
- 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

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DETAILED ACTION

Response to Arguments

1. Arguments filed in Paper No. 7, filed August 26, 2002 regarding the rejection of the claims under 35 USC 102 and 102/103 have been fully considered but they are not persuasive.

The response to the arguments is contained in the rejection repeated below.

2. Applicant's amendments to the claims in Paper No. 7 have overcome the objection to the claims in the previous office action, and the objection is withdrawn.

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 15-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 15 recites the limitation "the DNA containing butanol phase" in line 2. There is insufficient antecedent basis for this limitation in the claim.

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7. Claim 21 recites the limitation "the organic and aqueous phases" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 5, 6, 24, 28, 32, 33 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 03101688.

JP 03101688 taught (see the abstract) a aqueous mixture comprising a chaotrope (guanidinium salt) and butanol in a method of isolating plasmid DNA from an aqueous mixture of plasmid DNA and genomic DNA by adding a chaotrope (guanidinium salt) and butanol, then isolating the plasmid. The aqueous solution was at a basic pH.

10. Claims 1-12, 21-29, 32, 33, 36 and 38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over JP 03101688.

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JP 03101688 taught (see the abstract) a method of isolating plasmid DNA from an aqueous mixture of plasmid DNA and genomic DNA by adding a chaotrope (guanidinium salt) and butanol, then isolating the plasmid. The aqueous solution was at a basic pH.

JP 03101688 did not explicitly teach that the basic pH of the solution was produced by adding sodium hydroxide. However, sodium hydroxide is a notorious and well known basic reagent used to produce a basic pH in a solution containing plasmid DNA and genomic DNA as shown in WO 99/61603 (see especially page 12).

The instant specification teaches that n-butanol, 2-methylpropanol and butan-2-ol are obvious and well known forms of butanol, which would therefore be obvious to one of ordinary skill in the art at the time of filing the instant application, absent any unexpected results.

Response to Arguments

11. Arguments set forth in Paper No. 7 assert that the claims are drawn to extraction of plasmid DNA into butanol which separates the plasmid DNA from the genomic DNA. It is also asserted that JP 03101688 precipitates the DNA and the instant specification teaches that the plasmid DNA is recovered from the butanol (organic phase).

The claims do not assert that the plasmid DNA is separated from the genomic DNA. The instant rejected claims do not assert that the plasmid is extracted into an organic phase, nor that the butanol forms an organic phase which contains the plasmid DNA isolated from the genomic DNA. Since the claims do not set forth these limitations which are crucial for distinguishing the instant claims from the prior art, the arguments are not found convincing.

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12. Arguments set forth in Paper No. 7 assert that the Practical Example 4 in JP 03101688 is the only example which uses butanol and does not contain a plasmid.

The teachings of JP 03101688 are clear that butanol is to be used to extract DNA from a sample, and Practical Example 3 teaches the extraction of plasmid DNA from a sample. Therefore, the teachings of JP 03101688 are sufficient to anticipate, or in the alternative, make obvious the instant claims.

13. Arguments set forth in Paper No. 7 assert that WO 99/61603 does not provide teachings which are combinable with JP 03101688 to meet the requirements of 35 USC 103 for obviousness.

WO 99/61603 is merely used as a document to demonstrate that sodium hydroxide is well known and notorious to produce basic conditions in DNA containing solutions.

Allowable Subject Matter

14. Claims 13, 14, 30, 31, 34, 35 and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the William Phillips, whose telephone number is (703) 305-3482.

• William Sandals, Ph.D.
Examiner
November 15, 2002


TERRY McELVEY
PRIMARY EXAMINER